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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/706,255 | 11/12/2003 | Ondrej Hendl | 01068.US1 | 6868 |

25533 7590 05/30/2007
PHARMACIA & UPJOHN
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EXAMINER

TELLER, ROY R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1654

| MAIL DATE | DELIVERY MODE |
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05/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/706,255

Applicant(s)

HENDL ET AL.

Examiner

Roy Teller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 12, 13, 16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-13, 16-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This office action is in response to the amendment, received 3/21/07, in which applicant amended claims 12-13 and added new claims 16-17.

Claims 9-11 and 14-15 are withdrawn as being drawn to a non-elected invention.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-8, 12-13 and 16-17 are under examination.

Response to Amendments/ Arguments

Applicant's arguments and amendments filed 3/21/07 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-8, 12-13 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teagarden et al. (Pub.No. US 2002/0110561)

The claimed invention is drawn to a composition comprising one to three bioactive agents or specifically, crystalline ceftiofur free acid (CCFA) and one or more modified oils selected from corn oil, peanut oil, sesame oil, olive oil, palm oil, safflower oil, soybean oil, cottonseed oil, rapeseed oil, sunflower oil, as the liquid carrier and an un-modified liquid carrier wherein the ratio by volume of the modified liquid carrier to the unmodified liquid carrier is between 0.00001:99.99999 to less than 0.01: 99.99. "Modified" is understood to mean a vehicle which, through physical, chemical or mechanical means, has been altered as compared to its natural (or "non-modified" in the case of synthetic liquid carriers) form such that the modified vehicle has an increased level of oxidation products. Modification is accomplished by heat or irradiation, among other means.

Teagarden et al. discloses a composition comprising one or more bioactive agents, wherein said bioactive agent is crystalline ceftiofur free acid (CCFA) and a modified liquid carrier, wherein the modified liquid carrier includes a modified oil comprising a modified vegetable oil wherein said vegetable oil is selected from the group consisting of corn oil, peanut oil, sesame oil, olive oil, palm oil, safflower oil, soybean oil, cottonseed oil, rapeseed oil, sunflower oil and mixtures thereof wherein the ratio of modified unsaturated oil to saturated, non-oxidizing oil is from about 0.01:99.99 to about 90:10 (v/v). The composition wherein a said non-modified saturated oil or non-modified non-oxidizing vehicle comprises saturated coconut oil. See, i.e., for example, abstract, claims 1, 4, 6-10.

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The reference is relied upon for the reasons set forth above. If not expressly taught, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make result-effective adjustments in conventional working parameters (e.g., modifying the ratios by volume of the liquid carrier to the un-modified liquid carrier) as a mere matter of judicious selection and routine optimization, based upon the beneficial teachings provided by the cited reference. See MPEP 2144.05 (II).

Thus, the claimed invention as a whole is *prima facie* obvious over the cited reference, especially in the absence of evidence to the contrary.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT
1654
5/25/07

RT

Andrew D. Kesar 5/25/07
ANDREW D. KESAR
PATENT EXAMINER, ART UNIT 1654